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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/857,402	09/17/2001	Julio Cesar Aguilar Rubido	976-11 PCT/US	3056

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EXAMINER	
SALVOZA, M FRANCO G	
ART UNIT	PAPER NUMBER
1648	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/857,402	AGUILAR RUBIDO ET AL.	
	Examiner	Art Unit	
	M. Franco Salvoza	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15,16,21-23,38,39,41 and 42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15, 16, 21-23, 38, 39, 41, 42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 15, 38 have been amended.

Claims 15, 16, 21-23, 38, 39, 41, 42 are pending and under consideration.

Claim Rejections - 35 USC § 102

WITHDRAWN

Claims 15, 16, 21-23 were rejected under 35 U.S.C. 102(b) as being anticipated by Tabor et al. in light of Bowen et al.

Applicant contends that the HbcAg in Tabor et al. is not a nucleocapsid, rather an antigen without nucleic acid, thus Tabor et al. does not teach a nucleocapsid and teaches away from the use of HbcAg nucleocapsid.

Applicant's arguments are considered and found persuasive.

The rejection is withdrawn.

Claim Rejections - 35 USC § 103

WITHDRAWN

Claims 38-41 were rejected under 35 U.S.C. 103(a) as being unpatentable over Tabor et al. in light of Bowen et al. and further in view of Rose et al. and Hauser et al.

Claim 42 was rejected under 35 U.S.C. 103(a) as being unpatentable over Tabor et al. in view of McCluskie et al.

Applicant contends that in light of Tabor et al.'s lack of teaching of a nucleocapsid with nucleic acids that the base rejection falls.

Applicant's arguments are considered and found persuasive.

The rejection is withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 15, 16, 21-23, 38, 39, 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Milich et al. in view of Neurath et al. (U.S. Patent 6319501) with Chisari (U. S. Patent 5,932,224) cited in support.

Claim 15 recites a vaccine formulation suitable for mucosal administration comprising: (a) a mixture of a first vaccine antigen which is Hepatitis B virus surface antigen (HBsAg), and (b) a second vaccine antigen which is a viral nucleocapsid, wherein said HBsAg has an adjuvant effect on the second vaccine antigen, and wherein said first and second vaccine antigens are each present from 0.001mg to l mg.

Claims 16, 21, 22, 23 recite the vaccine formulation according to claim 15, wherein the viral nucleocapsid is the nucleocapsid antigen of Hepatitis B virus; wherein the vaccine formulation is suitable for use as a therapeutic vaccine against Hepatitis B virus (HBV) infection; wherein the vaccine formulation is suitable for use as a preventive vaccine against Hepatitis B virus (HBV) infection.

Claims 38, 39, 40 recite a vaccine formulation suitable for mucosal administration,

comprising: (a) a mixture of a first vaccine antigen which is Hepatitis B virus surface antigen (HBsAg), and (b) a second vaccine antigen and a third vaccine antigen wherein the second or third vaccine antigen is a viral nucleocapsid, wherein the vaccine antigens are each present from 0.001mg to l mg, wherein the HBsAg has an adjuvant effect on the second or third vaccine antigen; wherein the second vaccine antigen is an antigen of a viral nucleocapsid; wherein the third vaccine antigen is Hepatitis B virus core antigen (HBcAg).

Milich et al. teaches the use of nucleocapsid of Hepatitis B virus for use as antigen and vaccination for more efficient vaccination to elicit antibody production and activate T cells(p. 547, 549). HBcAg was administered to prime mice in concentrations including 4.0 μg (equivalent to 0.004 mg).

The position that "suitable for mucosal administration," "suitable for nasal administration," "suitable for use as therapeutic vaccine," "suitable for use as a preventative vaccine" are statements of intended use that to not structurally limit the composition is maintained.

Milich et al. does not teach wherein the formulation has a first vaccine antigen which is HBsAg present from 0.001mg to 1mg.

Neurath et al. teaches that adding HBsAg (including more specific residues) to subcutaneous (although other modes of delivery are encompassed (column 9, line 26) vaccine compositions results in improved vaccination, as well as teaching addition "one or more antigens" of HBsAg, which would teach a second vaccine antigen (in addition to a first HBsAg antigen).

Further, Chisari cited in further support teaches that it is desirable to combine Hepatitis B peptide vaccines for even more effective immune response (claim 15 recites a formulation comprising at least two components, thus could contain additional ones; additionally claim 38 recites formulation comprising at three components) with other components eliciting neutralizing antibodies, such as nucleocapsid-encoded antigens and HBsAg concurrently or in separate preparations; further, amounts desired are those that enhance the patient's own immune response capabilities and will vary depending on the patient's state of health and weight, the mode of administration, the nature of the formulation, etc. (columns 15-16; lines 34-02). Thus, the concentrations are asserted to fall within the parameters of routine optimization for administering effective vaccine compositions

One of ordinary skill in the art at the time the invention was made would have been motivated to combine the viral nucleocapsid antigen of Milich et al. and the HBsAg antigen(s) of Neurath et al. with Chisari cited in support because Neurath et al. and Chisari teachaddition of HBsAg to vaccine compositions improves vaccination.

One of ordinary skill in the art at time the invention was made would have had a reasonable expectation of success for using the viral nucleocapsid antigen of Milich et al. and the HBsAg antigen(s) of Neurath et al. with Chisari cited in support
because all teach using Hepatitis B antigens in
vaccination.

Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results to the contrary.

Claims 15, 16, 21-23, 38, 39, 41, 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Milich et al. in view of Neurath et al. with Chisari and McCluskie et al. in light of Carrano et al.

Claim 42 recites a method for administering a vaccine formulation to a mammal for generating an immune response, the method comprising administering mucosally to the mammal a vaccine formulation comprising: (a) a mixture of a first vaccine antigen which is Hepatitis B virus surface antigen (HBsAg), and (b) a second vaccine antigen which is a viral nucleocapsid wherein said HBsAg has an adjuvant effect on the second vaccine antigen, and wherein said first and second vaccine antigen are each present from 0.001 mg to 1 mg.

See the teachings of Milich et al. in view of Neurath et al. and Chisari above.

Milich et al. in view of Neurath et al. and Chisari do not teach a method for administering a vaccine formulation to a mammal for generating an immune response, the method comprising administering mucosally to the mammal a vaccine formulation.

See the teachings of McCluskie et al. in light of Carrano et al. as recited the previous Office Action on the Merits.

One of ordinary skill in the art at the time the invention was made would have been motivated to combine the composition of Milich et al. and Neurath et al. and Chisari in the method of McCluskie et al. and Carrano et al. because McCluskie et al. and Carrano et al. teach mucosal administration of Hepatitis B antigenic of compositions induce immune response.

One of ordinary skill in the art at time the invention was made would have had a reasonable expectation of success for using the composition of Milich et al. and Neurath et al. and Chisari in the method of McCluskie et al. and Carrano et al. because all teach administration

of Hepatitis B antigens to elicit immune responses against Hepatitis B.

Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results to the contrary.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to M. Franco Salvoza whose telephone number is (571) 272-8410. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

M. Franco Salvoza, Patent Examiner

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